DEC 27 2004

K042911

Cementek® LV
510(k) Summary
October 18, 2004

Submitter: Teknimed, S.A.
11 rue Apollo
31240 L'Union
FRANCE

Contact person: J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Trade Name: Cementek® LV

Common name: Bone void filler

Classification name: Class II per 21 CFR section 888.3045

Product Code: MQV

Equivalent Device: Cementek ® (K040669)

Device Description
As an injectable bone substitute, Cementek® LV is packaged as a solid phase and a liquid phase. The liquid and solid phases are mixed in the operating room, then introduced with a syringe into the osseous cavity and allowed to set. This reaction is an athermic reaction resulting in an apatitic calcium phosphate cement. Cementek® LV is marketed in a 16cc dosage.

Intended Use
Cementek® LV is intended for use only as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® LV is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be injected into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, the calcium phosphate scaffold resorbs and is replaced with bone during the healing process.

Summary of Technological Characteristics Compared to Predicate Device
Cementek® LV is equivalent to Cementek® in terms of physical form, how supplied, compressive strength, porosity, average pore size, composition of final product and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 27 2004

Teknimed, S.A.
c/o Mr. J.D. Webb
The Orthomedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, TX 78681

Re: K042911
Trade Name: Cementek LV Bone Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 6, 2004
Received: December 8, 2004

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042911

Device Name: Cementek® LV

Indications for Use:

Cementek® LV is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Cementek® LV is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to bone. The putty can be injected into the bony voids or gaps in the skeletal system (i.e. extremities, spine, and pelvis). Following placement in the bony voids or gap, Cementek® LV resorbs and is replaced with bone during the healing process.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhem

(Division Sign-Off)
Division of General, Restorative,
and Neurological D...

510(k) Number K042911